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(54) **A system for the control of dialysis.**

(57) A system for the control of dialysis and especially the ultrafiltration in connection therewith, comprising means for the connection of a dialyzer and means for the checking and control of the respective fluid flows on both sides of a membrane included in the dialyzer.

The invention primarily relates to a system for the control of haemodialysis, that is to say for the purifying of the blood of patients with diminished renal function or wholly lacking such function.

The system in accordance with the invention is characterized by two constant flow arrangements (18, 28) for the control of the dialysis fluid, one located before and one after the dialyzer (33), at least one of which is controllable so as to control the said ultrafiltration.

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A SYSTEM FOR THE CONTROL OF DIALYSIS

TECHNICAL FIELD

The present invention relates to a system for the control of dialysis and especially the ultrafiltration in connection therewith, comprising means for the connection of a dialyzer and means for the checking and control of the respective flows on both sides of a membrane included in the dialyzer.

The invention primarily relates to a system for the control of haemodialysis, that is to say for the purifying of the blood of patients with diminished renal function or wholly lacking such function. It will be obvious, however, to those versed in the art that the system in accordance with the invention also may be used for the control of dialysis in general.

BACKGROUND ART

More particularly the invention relates to a further development of the system which is marketed by the Gambro Group, to which the applicant belongs, under the description "Gambro AK-10".

Various details of this system form the subject of, for example, the US Patents: 4 122 010, 4 158 034, 4 293 409, 4 194 974 and 4 191 359, these descriptions being included hereby in the present description. Reference is made also to the further development according to European patent application 84.112914.1 and the invention according to the British patent 2 003 274 and the further development of this according to the European patent application published under number EP 0 106 940, and these too are included in the present description. Finally, reference is made to EP 0 022 922 which describes in more detail the preparation of dialysis fluid from two concentrates, a preparation which is only touched upon in the following description of the present invention.

DISCLOSURE OF INVENTION

The invention thus relates to a system of the abovementioned type which, more particularly, is characterized by two constant flow arrangements for the control of one or the other fluid flow -one located before and one after the dialyzer. By this design a very rapid control is made possible which can be carried out independently of the transmembrane pressure (TMP) which otherwise is frequently used for the control of the ultrafiltration, but which normally is a slow control factor owing, among other things, to the resilience of the membrane in the dialyzer.

Appropriately at least one of the two constant flow arrangements should be controllable so as to control the ultrafiltration. As will be evident from the following, however, another alternative is also possible.

Preferably the controllable constant flow arrangement comprises a pump and a constriction coupled in series and means for the measuring of a pressure which is a function of the pressure drop over the constriction and thus also of the flow through the same. Appropriately the said pressure consists of that in the flow between the pump and the constriction, whilst the pressure on the other side of the contraction preferably is held constant, e.g. at atmospheric pressure. In such a design the measured pressure may be used to control the capacity of the pump and this can be done in a fraction of a second. If the voltage of the motor is altered, the time from such an alteration of the voltage up to an alteration of flow may be in the order of magnitude of 0.1 s. As a result the system also can cope with pressure surges which in many systems known previously give rise to an ungovernable ultrafiltration.

The two constant flow arrangements appropriately are of essentially identical design and capacity but individually controllable independently of each other. This naturally simplifies the design at the same time as providing freedom to operate at varying total flow and varying pressure. The control as a whole, naturally, can also be made simpler if identical constant flow arrangements are used.

For reason of safety, means for measuring the pressure in the dialysis fluid flow are also provided, at least on one side of the dialyzer between this and the respective constant flow arrangement for checking and/or controlling the transmembrane pressure (TMP). At the same time, of course the blood pressure on the other side of the membrane is measured.

Appropriately the system in accordance with the invention also comprises means for the measurement of the dialysis fluid flow before and after the dialyzer. This means may be constituted, for example, of a differential measuring arrangement for the direct measurement of the difference in the fluid flow before and after the dialyzer respectively, this difference preferably being adapted so as to be integrated and used for the control of one or of both of the constant flow arrangements. The measuring system itself is described in greater detail in the two aforementioned publications GB 2 003 274 and EP 0 106 940.

Special advantages are gained if the said differential measuring arrangements are used to counteract slow alterations of the ultrafiltration, caused, for example, by membrane offset, whilst one or both constant flow arrangements are used for counteracting rapid alterations of the ultrafiltration, caused, for example, by accidental pressure surges. As a result an apparently very reliable control of the ultrafiltration is obtained which, moreover, will be substantially independent of accidental pressure surges.

Similar advantages, however, may be obtained by making use instead of the transmembrane pressure measured to counteract slow alterations of the ultrafiltration, caused e.g. by drift of the measuring instrument used, whilst one or both constant flow arrangements are used for counteracting rapid alterations of the ultrafiltration caused, for example, by accidental pressure surges.

In an alternative mode of realization of the subject of the invention the two constant flow arrangements are adapted so as to maintain the same constant flow, at the same time as the ultrafiltration is adapted so as to be controlled through withdrawal of the ultrafiltrate between them with the help of a controllable ultrafiltrate pump.

BRIEF DESCRIPTION OF DRAWINGS

The invention is described in more detail in the following with reference to the attached drawing which, by way of example, shows the most important components of a system in accordance with the invention.

BEST MODE OF CARRYING OUT THE INVENTION

In the system shown as an example in the attached drawing the water is fed via an inlet 1 to a heating device 2 where it is heated. The temperature is them measured in a temperature measuring device 3 before the water is conducted via a return vessel 4 to a constriction 5 and further via a bubble expansion tank 6, a pressure gauge 7 and a pump 8 to a vent tank 9. From the vent tank 9 a return duct 10 leads back to the return vessel 4 for recycling any air or other gases separated. A recycling would be possible instead to the heating vessel 2, but this would then require to be made from a more resistant material since dialysis concentrate is being supplied to the point 11 via the duct 12 with the help of the pump 13. This part of the system corresponds in substantial parts to the system which is described, for example, in the US patents 4 158 034 and 4 293 409. The function of the expansion vessel 6 is described in detail in the European patent application 84.112914.1. From the vent tank 9 the fluid is passed further via a conductivity measuring cell 14 to another mixing point 15 where further concentrate is supplied possibly with the help of a pump 16 and a duct 17. This is done on the assumption that it is intended to work with so-called two-component-based dialysis concentrate, e.g. of the type which is described in EP 0 022 922.

From the mixing point 15 the dialysis fluid is passed through a first constant flow arrangement 18 consisting of a constriction 19, a pump 20 and a pressure gauge 21. Before the constriction device 19 the pressure is substantially at atmospheric pressure as the duct is connected without any major resistance to the vent tank 9. Should it be found in practice that the pressure varies owing to the pump 16, the conductivity meter 14 and the mixing point 15 can be moved to a position before the vent tank.

The pressure measured by the pressure gauge 21 is used for the control of the pump 20, so that a desired constant flow is obtained. After the pump 20 the flow is passed through a conductivity meter 22 and an ultrafiltration monitor 23 via temperature measuring instrument 24 and a pressure gauge 25 to the dialyzer. From the dialyzer the flow is conducted via a pressure gauge 26, the said ultrafiltration monitor 23 and a blood detector 27 to a further constant flow arrangement 28 consisting of a pump 29, a pressure gauge 30 and a constriction device 31. Finally the dialysate is passed to an outlet 32. It is appropriate for the constant flow arrangement 28 to be identical with the arrangement 18. In the constriction 31, though, the pressure drop obtained is from a pressure above atmospheric to the pressure prevailing at the outlet which ought to be kept constant and, for example, may be equal to atmospheric pressure.

The design and the function of the ultrafiltration monitor are described in greater detail in the abovementioned publications GB 2 003 274 and EP 0 106 940.

Numeral 33 designates the dialyzer which can be connected to the system in accordance with the invention, on the blood side of which the patient is connected up. The latter connection, however, is not shown in the drawing. Finally, the broken lines show how ultrafiltrate can be withdrawn between the two constant flow arrangements 18 and 28 with the help of a pump 34 and possibly be collected in the receiver vessel 35. Hereby the ultrafiltration is appropriately controlled in that the two constant flow arrangements 18 and 28 are adapted to produce identical flows, so that the ultrafiltration can be wholly controlled with the help of the pump 34.

Naturally the invention is not limited merely to the embodiment described above, but can be varied within the scope of the following claims. For example, the diverse components included in the system can be varied within wide limits without the scope of the invention thereby being exceeded. Compare, for example, the publications cited above and the patent applications 85.02756-3 and 85.02758-9 with our references GA 139 and GA 141 submitted at the same time. Furthermore, it is possible, for example, instead of applying the invention to the dialysis fluid, to obtain similar advantages by arranging the two constant flow arrangements in the blood flow on either side of the dialyzer.

Claims

1. A system for the control of dialysis and especially the ultrafiltration in connection therewith, comprising means for the connection of a dialyzer and means for the checking and control of the respective fluid flows on both sides of a membrane included in the dialyzer, **characterized** by two constant flow arrangements (18, 28) for the control of one or the other fluid flow, one located before and one after the dialyzer (33).

2. A system in accordance with claim 1, **characterized** in that at least one of the two constant flow arrangements is controllable for the control of the ultrafiltration.

3. A system in accorance with claim 1 or 2, **characterized** in that the controllable constant flow arrangement (18 and/or 28) comprises a pump (20 or 29) and a constriction (19 or 31) coupled in series and means (21 or 30) for the measuring of a pressure which is a function of the pressure drop over the constriction (19 or 31) and thus also of the flow through the same.

4. A system in accordance with claim 3, **characterized** in that the said pressure consists of that in the flow between the pump (20 or 29) and the constriction (19 or 31), whilst the pressure on the other side of the constriction (19 or 31) preferably is kept constant, e.g. at atmospheric pressure.

5. A system in accordance with claim 3, **characterized** in that the measured pressure is used to control the capacity of the pum (20 or 29).

6. A system in accordance with anyone of the preceding claims, **characterized** in that the two constant flow arrangements (18, 28) are of essentially identical design and capacity, but individually controllable independently of each other.

7. A system in accordance with anyone of the preceding claims, **characterized** by means (25, 26) for measuring the pressure in the dialysis fluid flow at least on one side of the dialyzer (33) between this and the respective constant flow arrangement for the checking of TMP - (transmembrane pressure).

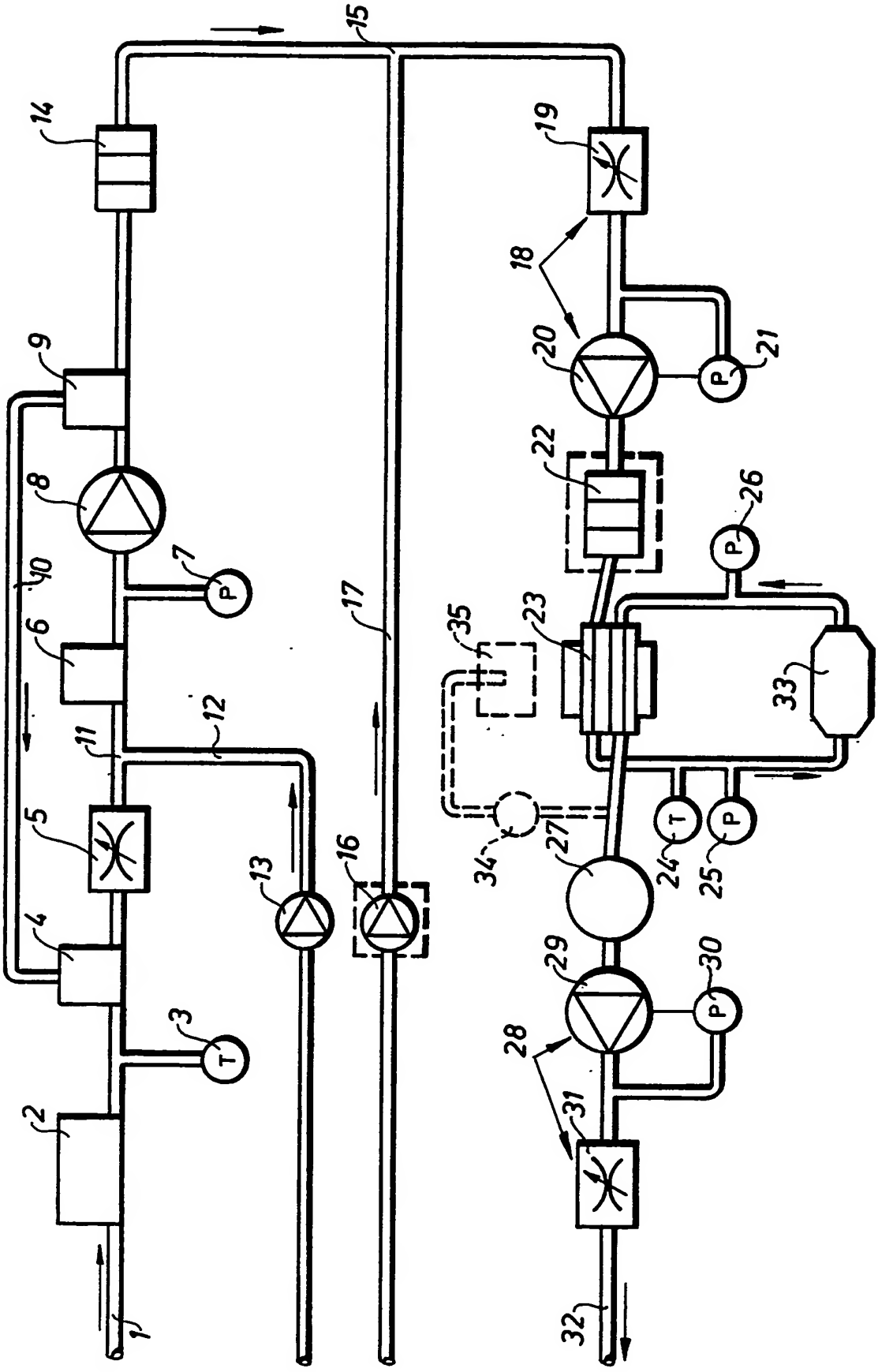
8. A system in accordance with anyone of the preceding claims, **characterized** by means (23) for measuring the dialysis fluid flow before äs well as after the dialyzer (33).

9. A system in accordance with claim 8, **characterized** in that the said means for the measurement of the dialysis fluid flow is constituted of a differential measuring arrangement (23) for the direct measurement of the difference in the fluid flow before and after the dialyzer (33) respectively, this difference preferably being adapted so as to be integrated and used for the control of one or of both of the constant flow arrangements (18, 28).

10. A system in accordance with claim 9, **characterized** in that the said differential measuring arrangement (23) is used to counteract slow alterations of the ultrafiltration, e.g. caused by membrane offset, whilst one or both constant flow arrangements (18 and/or 28) are used for counteracting rapid alterations of the ultrafiltration, e.g. caused by accidental pressure surges.

11. A system in accordance with claim 7, **characterized** in that the transmembrane pressure measured is used for counteracting slow alterations of the ultrafiltration, e.g. caused by drift of the measuring instrument used, whilst one or both constant flow arrangements (18 and/or 28) are used for counteracting rapid alterations of the ultrafiltration, e.g. caused by accidental pressure surges.

12. A system in accordance with claim 1, **characterized** in that the two constant flow arrangements are adapted so as to maintain the same constant flow and that the ultrafiltration is adapted so as to be controlled through withdrawal of the ultrafiltrate between them with the help of a controllable ultrafiltrate pump.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